## REMARKS

The Final Office action dated March 22, 2010 is acknowledged. Claims 1, 4-7 and 9 – 14 are pending in the instant application. Claims 1, 4-7 and 9-12 have been rejected and claims 13 and 14 have been withdrawn. By the present response, claim 1 recites a device for transdermal administration of active substance wherein the device has a plurality of needle-shaped microprotrusions for penetrating into the skin and where the microprotrusions are helically configured and rotatably arranged to facilitate penetration into the skin by applying a rotating movement. Moreover, claim 1 is amended to recite that the microprotrusions comprise a diffusible material for enabling the diffusion of the active substance(s) from the reservoir through the microprotrusions into the skin, support for which may be found throughout the specification such as at paragraph [000026]. Reconsideration is respectfully requested in light of the arguments made herein. No new matter has been added.

### Rejection of claims 1, 4-7 and 9-12 under 35 U.S.C. 103(a)

Claims 1, 4-7 and 9-12 have been rejected as being unpatentable over U.S. Publication No. 2002/0016562 (Cormier, et al.) in view of U.S. Publication No. 2004/0106904 (Gonnelli, et al.) and U.S. Publication No. 2005/0137525 (Wang, et al.). The Examiner states in the Final Office action that Cormier, et al. disclose a percutaneous agent delivery device for increasing transdermal flux of an agent and for improving attachment of the device to the skin, wherein the device has a plurality of microprotrusions for piercing and anchoring to the skin. Thus, the Examiner concludes that Cormier, et al. teach the presently claimed invention except for microneedles that are

helically configured and rotatably arranged, and does not expressly teach an adhesive that is coextensive with the microneedle plane.

The Examiner refers to Gonnelli, et al. for disclosing a microneedle device for the transport of drug molecules across tissue wherein an array of hollow microneedles is attached to a housing containing drug in an internal reservoir, the device further comprising a backing layer. The Examiner goes on to state that Gonnelli, et al. teach that the housing has a biadhesive coating around the microneedles and that an adhesive can be used to help secure the device to the tissue of the patient. Thus, the Examiner concludes that Gonnelli, et al. teach that the specific arrangement of the adhesive (e.g., coextensive) is merely a design choice that one skilled in the art would be readily able to make. The Examiner further explains that Gonnelli, et al. teach that the patient can remove a peel-away backing to expose an adhesive coating, that the microneedles may comprise plugs having barbs to catch biological tissue and that the plugs may have a cone or arrowhead shape to form barbed ends for gripping biological tissue and the use of poly/oligonucleotide drugs and vaccines.

The Examiner refers to Wang, et al. for disclosing rotating microneedle arrays that "drill" holes into a biological barrier. The Examiner also states that Wang, et al. teach that the microneedles can be hollow and the holes can be of controlled depth and are suitable for administering drugs. According to Wang, et al., it would be desirable to provide an improved system and method for controllably puncturing a tissue barrier for injecting/withdrawing materials and accomplishes this aim through the disclosed microneedle devices. The Examiner further states that Wang, et al. teach that the

microneedle arrays can be used for transdermal penetration by rotating the microneedles and that one salient feature of the microneedles of Wang, et al. is the ability of one more microneedles to rotate along a longitudinal axis while bearing down towards the biological barrier to be penetrated while such rotary motion facilitates a smooth, steady and controlled opening of a hole on the surface of the biological barrier. The Examiner also states that Wang, et al. teach that the microneedles can be driven by pneumatic or hydraulic actuators and the attachment of the microneedles to a reservoir.

The Examiner concludes that in light of the teachings of the prior art, it would have been prima facie evidence at the time of the invention to use at least some "rotatably arranged" microneedles in the device of Cormier, et al. with the motivation since Wang, et al. teach that rotating microneedles facilitate a smooth, steady and controlled opening in the skin and that such devices can improve the control of the depth of penetration into the skin. The Examiner also concludes that one skilled in the art would recognize that such a structure, added to the device of Cormier, et al., would provide the ability to selectively deliver drugs separately from those taught by Cormier, et al. that may be in the adhesive layer. Thus, the Examiner concludes that the combination of teachings of Cormier, et al., Gonnelli, et al. and Wang, et al. renders the presently claimed invention obvious.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references

when combined) must teach or suggest all of the claim limitations. The Applicant respectfully submits that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicant respectfully disagrees with the Examiner's conclusion for the numerous deficiencies of Cormier, et al., Gonnelli, et al. and Wang, et al. as set forth in the previous Office action response. Specifically, it would be clear to one skilled in the art that the microprotrusions of Cormier, et al. are neither helically configured nor rotatably arranged as presently claimed. In addition, Cormier, et al. do not teach or suggest any embodiment of their transdermal drug device which may comprise helically configured or rotatably arranged microprotrusions. Gonnelli, et al. do not teach that the microneedles are helically configured or rotatably arranged. Wang, et al. fail to teach providing a microneedle device with an adhesive polymer matrix which constitutes an active substance-containing reservoir, and which is arranged on the skin side of the device.

As currently amended, present claim 1 recites a device for transdermal administration of active substances, wherein the device comprises microprotrusions which are needle-shaped, have a longitudinal contour having at least one undercut for rendering extraction of the plurality of protrusions from the skin more difficult and for

fixing the device onto the skin, are helically configured and rotatably arranged, and are made of a diffusible material enabling diffusion of active substance from the reservoir into the skin. Thus, the microprotrusions of a device according to present claim 1 not only fix the device on the skin of the patient, but also improve administration of the drug from the reservoir of the device into the patient's skin because the active substance cannot only be transferred from the device to the patient's skin in the areas where the reservoir directly touches the skin, but also via the microprotrusions. Therefore, the contact surface between device and skin is increased such that administration of the active substance is improved.

It is submitted that none of the cited prior art references teach a device for transdermal administration of active substance, wherein the device comprises rotatably arranged microprotrusions which may also be utilized for drug delivery across the patient's skin. Moreover, none of the cited prior art teach or disclose wherein the microprotrusions comprise a diffusible material for enabling the diffusion of the active substance(s) from the reservoir through the microprotrusions into the skin.

The teachings of Cormier, et al., Gonnelli, et al. and Wang, et al., alone or in combination, fail to teach each and every limitation of the presently claimed invention, and thus fail to render the presently claimed invention obvious. In view of the above, it is clear that one skilled in the art would not be motivated to combine the teachings of said references or to modify the cited prior art references to arrive at the presently claimed invention. Even if one were to do so, each and every limitation of the presently claimed invention would not be taught or disclosed. Therefore, the Applicant respectfully

requests that the obviousness rejections be withdrawn.

## Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the anticipation and obviousness-type rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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By: _____
D. Peter Hochberg
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.
1940 East 6th Street, 6th Floor
Cleveland, OH 44114
(216) 771-3800